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GRANT NUMBER DAMD17-96-1-6070

TITLE: Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis

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REPORT DATE: July 1999

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	July 1999	Annual (1 Jun 98 - 31 May 99)

4. TITLE AND SUBTITLE
Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis

5. FUNDING NUMBERS
DAMD17-96-1-6070

6. AUTHOR(S)
Dr. Rena J. Pasick

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Northern California Cancer Center
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, MD 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200*

The current study, BACCIS-II, is a randomized controlled trial of an outreach intervention model designed to increase the rate of periodic mammography and clinical breast exam among underserved women. The purpose is to assess the feasibility and cost-effectiveness of BACCIS-II, a moderate level of intervention, compared retrospectively with the more intensive predecessor, BACCIS, and compared with a minimal (control group) intervention. In BACCIS, paid full-time outreach workers provided motivation, education and support to women over time, resulting in increased routine, periodic screening. However the model was very costly. In BACCIS-II, women in low-income communities are encouraged to become "links" to the community, volunteers who receive a modest incentive ($5 per eligible woman) to identify friends and family members at risk for late stage diagnosis (age 45+ and no mammogram past two years), and to provide their names to project staff . Women are then called by part-time staff who offer education, motivation and assistance in obtaining screening. Preliminary results show that the feasibility of the moderate level intervention is questionable since recruitment of women has fallen far short of expectations. However, once recruited, previously under- or unscreened women are getting mammograms (41%).

14. SUBJECT TERMS	15. NUMBER OF PAGES
Breast Cancer	56
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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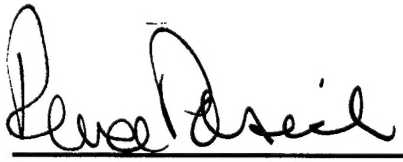

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ANNUAL REPORT

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I. INTRODUCTION

A. *Subject, Purpose and Scope of this Research*

The study "Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis", *BACCIS-II*[1], addresses two major gaps in the current state of knowledge for breast cancer outreach to underserved women: 1) absence of affordable, cost-effective interventions, and 2) interventions specifically intended to improve lifelong, periodic early detection practices, as distinct from only initial or one-time screening. In BACCIS-II, a moderate level outreach intervention (which retains the key strengths of more intensive original BACCIS, including woman to woman contact by trusted others from within the community and contact that is sustained over time to support and reinforce repeat screening) is tested for feasibility and cost-effectiveness in comparisons with a more intensive outreach intervention (the original BACCIS) and a minimal intervention (control group). The original research plan called for recruitment and randomization of 3200 women over a three year period. Due to much slower than anticipated recruitment (a function of the less intensive outreach model), the sample size was reduced to 1000 (a revised Statement of Work was approved 9/9/98).

However, because of continued slow recruitment, the trial was temporarily halted in October 1998 in order to modify the intervention model and to conduct a pilot test of the modified model. The trial resumed in December 1998 with improved recruitment, although still not on course for attainment of sample size objectives. Thus, the target numbers have again been reduced, and the intervention period extended. We now aim to recruit 500 women in all, a sample that is still more than sufficiently powered to evaluate the *effectiveness* of the model. Clearly, the *cost-effectiveness* will be adversely affected by this development.

II. BODY OF REPORT

A. *Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention*

In the last annual report (covering the 2nd project year, July 1, 1997 - June 30, 1998), we identified a number of difficulties with the outreach model and corrective action was underway. Recruitment at that time had improved. However, this improvement proved to be short-lived. The sections that follow summarize:

(i.) difficulties that then lead to a suspension of the trial in mid-October 1998;
(ii.) modifications made to the outreach protocol as a result; and
(iii.) accomplishments in an updated Statement of Work.

---

[1]The acronym "BACCIS-II" is derived from the predecessor to this research, the "Breast and Cervical Cancer Intervention Study", BACCIS, funded by the National Cancer Institute, 1991-1997. In the community, we have adapted our title and call the program the *Breast Cancer Community Information and Screening* project. In the research arena, we refer to it as BACCIS-II.

The modified protocol was pilot-tested, deemed feasible based on increased enrollment, and the trial resumed on December 8, 1998.

(i.) Summary of Problems Leading to Suspension of Trial

Agency Recruitment. At the last report we described considerable difficulty in agency recruitment (volunteers were to be recruited in teams of 4, each team being associated with a business, volunteer group, or other naturally occurring "agency"; teams were then randomized to intervention or control). We believed that additional staff training, focusing on ideal characteristics of prospective volunteer agencies, expansion of the geographic regions being targeted, and communication regarding the randomization process as well as modification to the agency criteria (groups greater than 4 were permitted as well as smaller groups, which were then combined and randomized as an agency unit) had resolved these problems. At the time the trial was suspended, 58 volunteers had been randomized to intervention (these were "Women's Health Leaders" or WHLs) and 26 were randomized to control (CILs or "Community Information Leaders"). The reason for the imbalance is that an equal number of teams had been randomized, but intervention agencies tended to have more volunteers per team. However, the modification to the protocol (described below) has improved this balance, with 52 volunteers randomized to intervention and 58 to control since the modification. Our fundamental problems now are not with agency recruitment (although this is still an intensive process since 366 agencies have been contacted to date to generate the current level of volunteers). Rather, the problems relate to training and motivation of volunteers who agree to participate.

Training. One of the major costs in the original BACCIS was the intensive and ongoing training that was required to keep paid outreach workers functioning at a high level of effectiveness. The plan for BACCIS-II was to reduce training to a minimum, but at a level still sufficient to equip women with the basic information and skills needed. This produced limited results and at the time of the last report (May/June 1998), our field staff (known as Community Educators - CEs) had begun going into the field with volunteers to personally demonstrate the elements of outreach. This proved effective, but as the numbers of women recruited show, when the CEs stopped going into the field with volunteers (late August and September), the rate of recruitment fell off precipitously (see Appendix A., Table 1.). We could not continue the practice of CEs in the field since that was too similar to the original BACCIS model. It is becoming clear that, just as women in underserved communities need ongoing support to continue getting mammograms, volunteers need ongoing support to continue finding and working with those women.

Volunteer Motivation/Incentives. Our original plan for volunteer incentives called for intervention teams to receive $500 for recruitment and yearlong follow-up with 80 women per agency. Control teams would receive $50 for recruitment only of 80 women per agency. Recruitment for both groups consisted of identifying qualified women (ages 45+ and no mammogram in the past two years) and completion of a baseline survey, self-administered by the respondent. In addition, volunteers in the intervention arm were to follow up with women according to our outreach protocol and, for the purpose of assessing cost for our cost-effectiveness analysis, were asked to complete a simple one-page follow-up form (Appendix B.) after each contact. This was designed to permit measurement of the time spent with each woman and the result of the contact. However, this task and management of the baseline survey proved onerous to women unaccustomed to such paperwork even though we tied

completion of the first follow-up form to receipt of incentives, which were distributed in $10 increments, upon receipt of two baseline surveys and one follow-up form per woman recruited. (Additional incentives were to be paid for completion of follow-up). As Table 2. In Appendix A. shows, submission of follow-up forms was inadequate, although it has been greatly improved and more consistent since the change in protocol at the end of 1998.

A second problem was the even slower recruitment of study participants into the control group (women who completed a baseline survey and received printed information on mammography but no personal follow-up) due to the very small monetary incentive to control group volunteers.

(ii.) Modifications to Protocol

With the disappointing enrollment in August and September 1998, the trial was suspended and staff set about devising adaptations to the protocol that would retain the integrity of the study design but eliminate the most problematic obstacles to outreach. Thus, the following modifications were pilot-tested in October and November:

1. *Elimination of volunteer responsibility for baseline survey.*
Under the modified protocol, volunteers are only responsible for identification of eligible women and obtaining the women's permission to relay their names and phone numbers to BACCIS staff who then call the women and administer the baseline survey over the phone. This task was difficult for all our volunteers but particularly for the less acculturated and less educated Latinas. In particular, staff are better able to administer the consent form and respond to questions regarding informed consent. Following completion of the consent and survey by phone, a copy of the consent form is mailed to every respondent.

Identification of at-risk women is the most time-consuming element of the outreach process, and if this could feasibly be done by volunteers working in conjunction with paid staff, the model might still prove more cost-effective than the more intensive model. For every name who proved eligible and willing to participate, the volunteers (now renamed "Links"... to the community), received an incentive of $5. Once a "Link" becomes active (refers the first eligible woman), she is randomized and all women referred by her go into the appropriate study arm. Thus, as before, randomization is by volunteer, not by participating respondent.

2. *Elimination of follow-up responsibility.*
A key element in encouragement of periodic screening among underserved women is establishment of a relationship that is maintained over time and involves the expression of concern and support around getting annual mammography. Because this involves following a protocol, simple though it is, and some record-keeping, this too was overly time-consuming for the amount of compensation offered and difficult for many volunteers. Thus, this responsibility has been turned over to BACCIS staff for women in the intervention arm only. This change does not affect the overall evaluation design, but will have an impact on the cost of the intervention.

3. *Modification of sample size.*
Our plan now is to continue the trial until we have enrolled 500 women. As described in detail in the

previous report, only 120 women per study arm are needed to adequately power an evaluation of the effectiveness of the intervention. However, since a primary concern is the cost-effectiveness of the intervention, we would like to have adequate time to assess costs in relation to effectiveness for the new protocol. Because this will take longer than originally planned to complete the intervention, we expect to continue our evaluation, analyses and reporting into a fifth year, a no-cost-extension. We are aiming to complete recruitment of the sample by mid-December 1999. Thus, the last women enrolled will receive their final evaluation interviews in February 2001 (14 months following the baseline survey, to allow time for one mammogram and then potentially a second). All analyses and reports will be completed by the end of June 2001.

We will increase the rate of randomization to the control group since thus far volunteers in both phases of the program, prior to the modification of the protocol and since, have been more enthusiastic about participating if they are assigned to the intervention (knowing that the women they refer will get more personal services). The rate of enrollment of respondents has been roughly two to one, intervention to control. Thus, we are now randomizing three "Links" to control for every one randomized to intervention, and will continue to adjust this ratio as needed.

4. *In-depth assessment of the volunteer experience.*
Upon completion of the recruitment, we will convene a series of focus groups in order to develop a comprehensive explanation for the variations in volunteer activity. We will convene one Spanish language group with volunteers who have been very active, and one with those have not, and corresponding English language groups (with African American and white volunteers). The discussion will focus on barriers and facilitators of the outreach process.

B. ***Technical Objectives: Evaluate cost-effectiveness of three levels of intervention***

We are on track with our proposed time line and expect to complete the analyses as scheduled. We have, however, made some modifications to the original proposal to reflect the evolution of the project (discussed below).

In Year 4, we will finish the CEA for BACCIS-I and prepare a manuscript for submission to a professional journal. Draft sections of this paper have been prepared, but completion of the paper will require the following tasks:

- Completion of the analysis of costs and effectiveness
- Calculation of cost-effectiveness ratios and sensitivity analyses
- Write-up of the introduction, methods, results, and discussion sections, which will require an updated review of the literature and the integration of other papers on BACCIS-I
- Circulation of the draft paper to the research group for comments
- Completion of revisions and preparation for submission

In Year 4 we will also prepare a manuscript that discusses the issues involved in evaluating the costs and effectiveness of community-based interventions such as BACCIS-I and BACCIS-II. We have learned a great deal about the challenges involved in evaluating interventions and approaches to overcome them, so that these "lessons learned" can be applied to future

interventions.

Lastly, we will prepare a final report that summarizes the analyses discussed above.

(i.) Estimating the Effectiveness of BACCIS-I

We primarily focused on estimating the effectiveness of BACCIS-I, which proved to be a complex undertaking. When we proposed this study, we had assumed that the effectiveness of BACCIS-I would already have been determined and that papers from that intervention would have been completed. However, this was not the case. Therefore, we spent a great deal of time conceptualizing our measures of effectiveness and actually analyzing the data. Although this was a time-consuming activity, our results have proved useful not only for this analysis but also for other analyses being conducted of BACCIS-I and ongoing interventions.

Measuring the effectiveness of BACCIS-I is complicated by two factors. First, there are two relevant data sets: (1) the personal contact form database based on the intervention participants; and (2) the household survey database, based on the two random household surveys. Both data sets are necessary to fully measure the effectiveness of BACCIS-I and considerable effort has been devoted to reconciling these data, conducting, and refining our data analyses.

Second, BACCIS-I had multiple outcomes: number of women contacted, number of women obtaining screening, and number of women achieving maintenance. Furthermore, for each of these outcomes, we had data from both data sets. Therefore, we had to determine which outcomes and datasets to use for our primary analyses. The end result has been an innovative approach that has applications to other interventions. In sum, our analysis is one of the few that will be able to incorporate into the CEA not only the direct effects of the intervention but also the indirect or "spillover" effects. Although from a conceptual perspective it is always correct to consider spillover effects, most prior CEAs have not been able to quantify these effects using actual data. Rather, most CEAs have had to rely on models that attempt to estimate these effects (e.g., using decision trees). The availability of actual data greatly strengthens our analysis and provides an example for future studies.

(ii.) Estimating the Cost-Effectiveness of BACCIS-II

We have also spent a great deal of time with the BACCIS-II team discussing the intervention and how to improve it. When we wrote the proposal, we assumed that BACCIS-II would be implemented as planned and therefore we could calculate the costs and effectiveness during the implementation. Because the intervention has evolved over time, it is has proven difficult thus far to obtain cost and effectiveness data from this "moving target". We will attempt to distinguish the two main phases of the intervention, before and after the modification of the protocol, when analyzing cost and effectiveness data. Due to the poor feasibility of recruitment to date, it is likely that the moderate level BACCIS-II intervention will not be shown to be cost-effective.

Yet, as discussed elsewhere in the report, we have learned a great deal about the issues involved

in evaluating the costs and effectiveness of community-based interventions such as BACCIS-I and BACCIS-II. These "lessons learned" are of even greater importance than the actual CEA, since they can be applied to the design and conduct of future interventions. We will therefore write a manuscript based on these "lessons learned". This manuscript will discuss issues such as the comparison of different interventions, the use of time diaries, the measurement of spillover effects, and the use of retrospective vs. prospective data.

III. Summary of Accomplishments Associated with Each Task from Approved Statement of Work

Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention

Task (as Originally Proposed)	Status as of Last Report	Current Status
1. Adapt/pre-test BACCIS model	complete	
2. Develop/pre-test baseline survey	complete	
3. Recruit 20 businesses/agencies/ organizations (intervention arm numbers only)	reduced to 15	- concept of agency has been modified; recruitment is in progress and on track
4. Train 80 Women's Health Leaders by month 9	reduced to 60 by month 30	- concept of Women's Health Leader has been modified; to date, 110 have been randomized to intervention
5. Enroll & follow-up 1600 women in each of intervention & control by month 40	objective reduced to 500 in each arm	- enrollment to date: 208 intervention 106 control - objective reduced to 500 total by month 43
6. Complete final survey* of 3200 women by month 43	reduced to 1000	- objective reduced to 500 by month 55
7. Complete process evaluation analyses by month 43	not initiated	- underway; completion will correspond with revised end of intervention: month 53
8. Analyses and reporting on baseline to follow-up changes by month 48	not initiated	- revised completion, month 60

* Final survey instrument has been developed, pre-tested and approved by the NCCC Institutional Review Board. See Appendix C for Spanish and English instrument and IRB approval.

Technical Objectives: Evaluate cost-effectiveness of three levels of intervention

Task (as Originally Proposed)	**Status as of Last Report**	**Current Status**
9. Research relevant literature	complete	
10. Develop cost-effectiveness analysis design	in progress	complete
11. Develop data collection approaches and instruments	in progress	in progress
12. Monitor collection of intervention cost data and effectiveness data	in progress	in progress
13. Develop analytic model and input data	not initiated	in progress
14. Complete societal and organizational analyses and reporting	not initiated	in progress

III. Key Research Accomplishments

- To date, 110 volunteers have been randomized to intervention and 84 to control.

- To date, 56 (41%) women in the BACCIS-II intervention have received mammograms as part of the intervention. 22 of these women (39%) had never before had a mammogram. 17 (77%) of the women receiving their first mammogram were fifty years old or older.

- To date, 6 women in the BACCIS-II intervention have received their **second** mammogram as part of the program. This is a very exciting development, since only 33 women have been enrolled in the program long enough to be eligible for a second mammogram. This reflects progress toward our primary goal of encouraging routine periodic screening.

- While still the trial is still in progress, we expect to produce findings that inform realistic expectations regarding the labor intensive and costly process of outreach to underserved women aimed at increased use of mammography and clinical breast exam.

IV. Reportable Outcomes

- A first manuscript on the cost-effectiveness analysis of BACCIS-I is under development for submission during the current year.

- Further outcomes await conclusion of the intervention.

V. Conclusions

Until the study is complete, we cannot conclude how effective the intervention has been in comparison with the control condition. However, we can draw one preliminary conclusion regarding the feasibility of the intervention: *Outreach to underserved women using lay health workers **is** time-consuming and costly. There may be no way of streamlining recruitment and education of women through this mechanism.* Furthermore, intensive and ongoing support of lay health workers is required and modest monetary incentives do not compensate for lack of such support and training.

Other preliminary conclusions address the complexity of conducting randomized clinical trials in the community.

First, among underserved communities, it is very difficult to conduct a randomized trial. Those less educated and/or less acculturated often do not understand or value the concept of evaluation and how it is best done.

Second, the record-keeping required to conduct evaluation and cost-effectiveness analyses can and does interfere with the intervention, thus impeding assessment of effectiveness. It is possible that the intervention we have developed may be more feasible in the absence of a baseline survey and follow-up paperwork.

Appendix A.
Selected Process Evaluation Data To Date

Table 1.
Baseline Interviews Completed by
Month and Study Arm

Table 2.
Follow-Up Forms Submitted by Month &
Data on Receipt of Mammogram From Follow-up Forms
(Intervention Arm Only)

Table 1.
Baseline Interviews Completed by Month and Study Arm

1997

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Control										3	4	0	7
Intervention										1	0	0	1
										4	4	0	8

1998

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Control	1	2	0	5	3	12	12	10	1	1	6	2	55
Intervention	2	0	6	5	19	45	6	3	0	1	6	18	111
	3	2	6	10	22	57	18	13	1	2	12	20	166

1999

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Control	2	5	12	9	12	4							44
Intervention	9	24	17	21	9	16							96
	11	29	29	30	21	20							140

Total Intervention: 208
Total Control: 106
TOTAL ENROLLED TO DATE: 314

Table 2.
Follow-Up Forms Submitted by Month &
Data on Receipt of Mammogram From Follow-Up Forms
(Intervention Arm Only)

1998

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
	0	0	1	3	7	35	35	4	1	0	41	7	134

1999

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
	35	49	22	24	25	28							183

Total forms to date = 317

Number of Women in Intervention = 208

Number of Women Followed to Date = 136

NUMBER OF WOMEN WHO HAVE RECEIVED A MAMMOGRAM = 56

NUMBER OF WOMEN WHO HAVE RECEIVED TWO MAMMOGRAMS = 6

Appendix B.
Follow-Up Form (English and Spanish)

BACCIS

FOLLOW-UP FORM

(Complete every time you talk to a woman after you invite her to get a mammogram.)

WHL _____ WOMAN'S BACCIS ID# _____

WOMAN'S NAME _____ TODAY'S DATE _____

TYPE OF CONTACT:

☐ Phone call How many times did you try before reaching her? _____

☐ In person
Where: _____

Length of this call/visit:
hours _____ minutes _____

REASON FOR CALL	ANSWER	TO DO
☐ to see if she **made** *appointment* with ***doctor***	☐ Yes (appt. date:_____) →	Call to remind 2 days before
☐ to **remind** her of *appointment* with ***doctor***	☐ No →	Call again in 1 week to encourage
☐ to see if she **kept** *appointment* with ***doctor***		

☐ to see if she **made** *appt.* for *mammogram*	☐ Yes (appt. date:_____) →	Call to remind 2 days before
☐ to **remind** her of *appt.* for *mammogram*	☐ No →	Call again in 1 week to encourage
☐ to see if she **kept** *appt.* for *mammogram*		

☐ Did she get a mammogram?	☐ Yes →	Congratulate her
	☐ No →	Invite her to get one and start over

☐ to help with a problem (what is it?) _____ _____ _____	☐ woman refuses →	CALL BACCIS at (510) 374-7175

Remember - always note your next call on your reminder list.

OFFICE COPY (TO MAIL)

FOLLOWUP (2/6/98)

BACCIS

FORMA DE SEGUIMIENTO

(Complete cada vez que hable con la señora después que la haya invitado a obtener un mamograma.)

WHL _____ SEÑORA DE BACCIS ID# _____

NOMBRE DE LA SEÑORA _____ FECHA _____

TIPO DE CONTACTO:

☐ Llamada teléfonica ¿Cuántas veces llamó antes de hablar con ella? _____

☐ En persona
Adónde: _____

Duración de la llama da/visita:
horas _____ minutos _____

RAZÓN DE LA LLAMADA	RESPUESTA	QUÉ HACER
☐ para ver si **hizo** una *cita* con el ***doctor***	☐ Sí (fecha de la cita _____) →	Llame 2 días antes para recordarle
☐ para **recordarle** de la *cita* con el ***doctor***	☐ No →	Llame otra vez en una semana para motivar a la señora
☐ para ver si **fué** a la *cita* con el *doctor*		

☐ para ver si **hizo** una *cita* para el *mamograma* ☐ para **recordarle** de la *cita* para el *mamograma* ☐ par ver si **fué** a la *cita* para el *mamograma*	☐ Sí (fecha de la cita _____) →	Llame 2 días antes para recordarle
	☐ No →	Llame otra vez en una semana para motivar a la señora

☐ Obtuvo la señora un mamograma?	☐ Yes →	Felicítela
	☐ No →	Invítela a que obtenga uno y empieze de nuevo

☐ para ayudarle con un problema (Cuál es?) _____ _____ _____	☐ Si la señora no acepta →	Llame a BACCIS al # 374-7175

Recuerde - siempre anote su próxima llamada en su lista de recordatorios.

COPIA DE OFICINA
(envie por correo con cuestionario)

Appendix C.

Final Survey Instrument (English and Spanish)

NCCC Institutional Review Board Approval

Information for BACCIS Participants

Hello Mrs./Ms./Miss_____. I am calling from BACCIS, the women's health program in Contra Costa County. You may remember filling out one of our surveys just about one year ago. Thank you very much for your involvement in our program.

I am calling today to ask you to complete one more 10 to 15 minute survey by phone that will help us learn how the women we have reached are doing. Your assistance is especially important because this program is trying to help women learn more about cancer screening. This survey is the last part of our program.

First, I would like to tell you about your rights as a participant in this survey. This is strictly voluntary. You may refuse to answer any questions. No medical care or other services are dependent on your participation. The information you provide will be strictly confidential. Your name will not be used in connection with this information or given to anyone outside our program. All personal information will be kept in a locked case with names deleted. There is no risk to you from your participation in this program. However, the federal government agency who is our sponsor has a rule that we must inform you that any injury that happens to you because of your participation will be paid for.

There are no additional costs to you for participating in this program. However, you will benefit by helping us to learn more about the health needs of women in your community so that better programs can be developed.

I am going to mail you a copy of this information for your records. If you would like more information, you may contact:
Dr. Rena Pasick
Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600
Union City, CA 94587
(510) 429-2500

Also, information about your rights as a program participant can be obtained from:
NCCC IRB Chairman Anthony Ubalde
Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600
Union City, CA 94587
(510) 429-2500

Project Title: Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis

Participant Name: _____
(Please Print)

Read over telephone: Staff initials _____ Date _____

BACCIS-II Final Survey

1. Woman's name _____ / ID# _____

Interviewer Initials: _____ Date of Interview: _____

May I begin my questions?

2. Before today, have you ever heard of a mammogram? (A mammogram is an x-ray of the breasts using a machine that presses the breast).
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

3. Have you ever had a mammogram?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

[If YES]:

a. About how long ago did you have your last mammogram?

Years _____ (Less than one year = 00) (2 digit year code)

[IF LESS THAN ONE YEAR, RECORD HOW MANY MONTHS]:

Months _____ (01-12)

b. How many mammograms have you had in the last 5 years? _____

[If in the past year]:

c. Was your last mammogram normal, or did you have to have more tests?
   1. Normal **[GO TO 4]**
   2. More tests
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

[IF MORE TESTS];

d. What was the result of those tests?
   1. **[DON'T READ]** CANCER
   2. **[DON'T READ]** CANCER SUSPECTED
   3. **[DON'T READ]** BENIGN (NO PROBLEM)
   6. **[DON'T READ]** OTHER **[SPECIFY]:** _____
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

4. Do you plan to have a mammogram in the next 12 months?
   1. Yes
   2. No **[GO TO Q5]**
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

[If YES]:

4a. Do you plan to continue having a mammogram every year?
   1. Yes **[GO TO Q5]**
   2. No **[GO TO Q5]**
   7. **[DON'T READ]** NOT APPLICABLE **[GO TO Q5]**
   8. **[DON'T READ]** DON'T KNOW/NOT SURE **[GO TO Q5]**
   9. **[DON'T READ]** REFUSED **[GO TO Q5]**

5. Do you know where to go if you wanted a mammogram this month?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

6. Have you ever had a breast exam by a doctor or nurse? A breast exam is when a doctor or nurse feels for lumps in your breasts?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

[IF YES]:

6a. About how long ago did you have your last breast exam?
Years _____ (Less than one year = 00) (2 digit year code)

[IF LESS THAN ONE YEAR, RECORD HOW MANY MONTHS]:
Months _____ (01-12)

7. Is there one doctor that you usually see when you are sick or need a check up?
    1. Yes
    2. No
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

8. My next questions are things people sometimes say about mammograms. These are opinions and there are no right or wrong answers. Please tell me if you agree or disagree?

a. You don't need a mammogram if you've had a breast exam from a doctor or a nurse. Do you agree or disagree with that statement?
    1. Agree
    2. Disagree
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

b. Mammograms can lead to breast surgery that is not needed.
    1. Agree
    2. Disagree
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

c. You would have a mammogram if your doctor told you that it's important.
    1. Agree
    2. Disagree
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

d. You won't have a mammogram if it takes more than an hour to get there. Do you agree of disagree with that?
    1. Agree
    2. Disagree
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

e. Having a mammogram every year will give you a feeling of control over your health.
    1. Agree
    2. Disagree
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

f. You will only get a mammogram if you have a breast problem.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

g. Mammograms are a very common medical test.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

i. It will be good for your family if you have a mammogram.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

j. Regular mammograms give you peace of mind about your health.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

k. A mammogram is just a good way to take care of yourself.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

l. A woman should get a mammogram even if there is no breast cancer in her family.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

m. Mammograms work best when you have one every year.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

n. Mammograms are safe.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

o. You are too busy to have a mammogram.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

p. Do you agree or disagree with <u>this</u> statement:
   Mammography is not a useful test for women your age.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

q. Mammograms cost too much for you.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

r. A mammogram might hurt or be uncomfortable.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

s. You're just not worried about breast cancer.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

t. You don't need a mammogram because you're healthy. Do you agree or disagree with that?
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

u. Getting a mammogram is just too much trouble.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

v. Do you agree or disagree that:
   You don't need a mammogram at your age.
   1. Agree
   2. Disagree
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

9. During the past 12 months, has anyone from our BACCIS program talked to you about getting a mammogram? (Someone who might have given you the white, flat, magnetic BACCIS pen or sent it to you in the mail? Also, someone might have called from our program...do you recall that?)
   1. Yes
   2. No **[GO TO Q10]**
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

[If YES]:

a. Did you like talking to that person?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

b. Was she helpful to you?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

c. Did she convince you to get a mammogram?
   1. Yes
   2. No
   7. **[DON'T READ]** NOT APPLICABLE
   8. **[DON'T READ]** DON'T KNOW/NOT SURE
   9. **[DON'T READ]** REFUSED

10. During the past 12 months, has any <u>other</u> woman you know talked to you about getting a mammogram?

    1. Yes
    2. No **[GO TO Q11]**
    7. **[DON'T READ]** NOT APPLICABLE **[GO TO Q11]**
    8. **[DON'T READ]** DON'T KNOW/NOT SURE **[GO TO Q11]**
    9. **[DON'T READ]** REFUSED **[GO TO Q11]**

a. Was she a volunteer with our program?

1. Yes
2. No **[GO TO Q11]**
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED **[GO TO Q11]**

[If YES or NOT SURE]:

b. Did she convince you to get a mammogram?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

11. During the past 12 months have you tried to get a free mammogram?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

[If YES]:

11a. Were you eligible (able to get the mammogram for free)?

1. Yes
2. No **[ASK 11b.]**
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

[If NO]:

11b. What was the reason? (Select **ALL THAT APPLY**)

1. **[DON'T READ]** Age
2. **[DON'T READ]** Income
3. **[DON'T READ]** Other **(SPECIFY):** _____

12. These are questions about health insurance. Please answer yes or no for each choice. Do you have:

a. Medicare (This is a health plan from the government to pay for medical expenses for people 65 and older, or people with a disability)

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

b. MediCal (This is a health plan from the state government to pay for medical expenses for people with low income or a disability)

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

[If YES to MediCal]
Do You Have:

(i) Contra Costa Health Plan
1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

(ii) Foundation Health Plan
1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

Do you have:

c. Health insurance that you, your family, or your employer pays for?

1. Yes [Name of Company: _____]
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

d. Basic Adult Care (BAC from Contra Costa County)

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

e. [If ALL Nos to 12a through d] According to everything you have told me, you do not have health insurance of any kind. Not including dental or vision care, do you have health insurance that pays for doctor visits through a plan that I might have missed?

1. Yes [Name of Company: _____]
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

13. When you go to the doctor, do you have to pay with your own money?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

I just have a few more questions.

14. In what country were you born?

1. United States **[SKIP TO 15]**
2. Mexico
3. Cuba
4. El Salvador
5. Colombia
6. Argentina
96. Other **[SPECIFY]:** _____
97. **[DON'T READ]** NOT APPLICABLE
98. **[DON'T READ]** DON'T KNOW/NOT SURE
99. **[DON'T READ]** REFUSED

14a. How old were you when you first came to live here in the United States?

_____ Age of arrival (If less than 1 year, code - 0. Logical range = 1-90)

97. **[DON'T READ]** NOT APPLICABLE
98. **[DON'T READ]** DON'T KNOW/NOT SURE
99. **[DON'T READ]** REFUSED

14b. In total, how many years have you lived in the United States?

_____Years (If less than 1 year, code = 0. Logical range = 1-90)

97. **[DON'T READ]** NOT APPLICABLE
98. **[DON'T READ]** DON'T KNOW/NOT SURE
99. **[DON'T READ]** REFUSED

15. In general, what language(s) do you speak? **[Choose all that apply]**

1. English _____
2. Spanish _____
3. Other **[SPECIFY]:** _____

[If speaks language other than/in addition to English]:

15a. How well do you speak English?

1. Not at all
2. Poorly
3. So-So
4. Well
5. Fluently, like a native
8. **[DON'T READ]** Don't know/not sure
9. **[DON'T READ]** Refused

b. In general, what language(s) do you read?

1. English only
2. Spanish (or other language) better than English
3. Both equally
4. English better than Spanish (other language)
5. Only Spanish (other language)
6. Other **(SPECIFY):** _____
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** Don't know/not sure
9. **[DON'T READ]** Refused

c. What language(s) do you usually speak at home?

1. English only
2. Spanish (or other language) better than English
3. Both equally
4. English better than Spanish (other language)
5. Only Spanish (other language)
6. Other **(SPECIFY):** _____
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** Don't know/not sure
9. **[DON'T READ]** Refused

d. What language(s) do you usually speak with your friends?

1. English only
2. Spanish (or other language) more than English
3. Both equally
4. English more than Spanish (other language)
5. Only Spanish (other language)
6. Other **(SPECIFY):** _____
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** Don't know/not sure
9. **[DON'T READ]** Refused

16. How many years of school did you finish?

IF Respondent says [grade level], Code as follows:
Elementary = 6; Junior High = 8; High School/GED = 12; Some college/Vocational School =14; College Graduate = 16; Master's Degree = 18; MD, PhD, JD, DDS = 20

_____ Years

17. Do you own your home?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

18. In total, including yourself, how many people live in your household?

_____ Number of Persons

97. **[DON'T READ]** NOT APPLICABLE
98. **[DON'T READ]** DON'T KNOW/NOT SURE
99. **[DON'T READ]** REFUSED

19. These are my last questions. Now I am going to ask you about your household income. It may be hard to estimate this income, but do your best. This information will be strictly confidential. Taking all the income of all the members of your household (wages, Social Security, retirement or pensions, unemployment benefits and disability), which of these categories best fits your total household income for last year (1998)? Is it:

1. Less than $5000
2. $ 5,000 to less than 10,000
3. $10,000 to less than 20,000
4. $20,000 to less than 30,000
5. $30,000 to less than 40,000
6. $40,000 to less than 50,000
7. $50,001 or more
97. **[DON'T READ]** NOT APPLICABLE
98. **[DON'T READ]** DON'T KNOW/NOT SURE
99. **[DON'T READ]** REFUSED

20. Are you receiving SSI (Supplementary Security Income or the gold check)?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

That's the end of my survey, but I'd like to know if:

21. You need any help to get a mammogram now?
    1. Yes
    2. No
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

21a. **[If YES:]** Shall I have one of our staff call you in the next couple of weeks?

1. Yes
2. No
7. **[DON'T READ]** NOT APPLICABLE
8. **[DON'T READ]** DON'T KNOW/NOT SURE
9. **[DON'T READ]** REFUSED

Thank you very much for completing these questions.

22. Would it be alright if we contact you again sometime for another survey?

    1. Yes
    2. No
    7. **[DON'T READ]** NOT APPLICABLE
    8. **[DON'T READ]** DON'T KNOW/NOT SURE
    9. **[DON'T READ]** REFUSED

Thank you again for your time.

Interviewer comments:

_____ Interviewer _____ Date

Información para Participantes de BACCIS

Hola Sra./Srta._____. Estoy llamando de BACCIS, el programa de salud para mujeres en el Condado de Contra Costa. Usted se recordará haber llenado uno de nuestros cuestionarios más o menos hace un año, en el que usted nos dio su nombre y número de teléfono y nos dijo que la podíamos llamar otra vez.

Esto es parte de un estudio investigativo conducido por la doctora Rena Pasick del Centro de Cancer del Norte de California.
Muchas gracias por su participación en nuestro programa.

La estoy llamando ahora para pedirle que complete otro cuestionario de 10 a 15 minutos de duración que nos ayudará a aprender como las mujeres participantes están haciendo. Su asistencia es especialmente importante porque este programa está tratando de ayudar a mujeres a aprender más acerca de los exámenes rutinarios del cáncer. Este cuestionario es la última parte de nuestro programa.

Primero, me gustaría decirle sus derechos como participante en este cuestionario. Esto es estrictamente voluntario. Usted puede rehusar contestar cualquier pregunta. Ningún servicio médico u otros servicios dependen de su participación. La información que usted nos dé será muy confidencial. Su nombre no se usará en conección con esta información y no se le dará a nadie fuera de nuestro programa. Toda información personal será guardada bajo llave sin nombres. El único riesgo posible para usted por su participación en este programa es su tiempo y que algunas preguntas pueden ser de alguna manera delicadas. Una vez más, usted se puede rehusar a contestar cualquier pregunta.

No hay costo alguno para usted por su participación en este programa. Sin enbargo, usted se beneficiará al ayudarnos a aprender más acerca de las necesidades de salud de las mujeres en su comunidad, ya que mejores programas serán desarrollados.

Yo puedo enviarle una copia de esta información si usted asi lo desea. Si usted desea más información, se puede comunicar con:
Dr. Rena Pasick
Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600
Union City, CA 94587 (510) 429-2500

También puede obtener información acerca de sus derechos como participante del programa en:
NCCC IRB Chairman Anthony Ubalde
Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600
Union City, CA 94587 (510) 429-2500

Título del Proyecto: Breast Cancer Outreach For Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis

Nombre de la Participante: _____

Lea por teléfono: Iniciales de Personal _____ Fecha _____

BACCIS-II Cuestionario Final

1. Nombre de la señora_____/ID#_____

Iniciales de entrevistadora:___ Fecha de entrevista:_____

¿Puedo empezar con las preguntas?

2. Antes de ahora, ¿Alguna vez había oído de un mamograma? (Un mamograma es rayos-x de los senos usando una máquina que presiona los senos).

   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

3. ¿Se ha hecho usted un mamograma alguna vez?

   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

[Si su respuesta es SI]:

a. ¿Cuándo fue su último mamograma?

Mes_____ Año_____
(01 - 12) (2 digitos para el codigo del año)
[*Note for #5, if not last 2 years]**

b. ¿Cuántos mamogramas se ha hecho en los últimos 5 años?_____

[Si obtuvo uno el año pasado]:

c. Fue su mamograma normal , ¿ o tuvo que tener más exámenes?

   1. Normal
   2. Más exámenes
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

[SI LE HICIERON MÁS EXÁMENES]:

d. ¿cuál fue el resultado de esos exámenes?

1. **[NO LEA]** Cáncer
2. **[NO LEA]** Sospechas de cáncer
3. **[NO LEA]** Otro **[ESPECIFIQUE]:**_____
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

4. ¿Planéa hacerse un mamograma en los próximos 12 meses?

1. SÍ
2. No **[PASE A LA PREGUNTA 5]**
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

[SI SU RESPUESTA ES SÍ]:

4a. ¿Piensa usted que podría hacerse un mamograma cada año?

1. Si **[PASE A LA PREGUNTA 6]**
2. No **[PASE A LA PREGUNTA 6]**
7. **[NO LEA]** NO APLICA **[PASE A LA PREGUNTA 6]**
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA **[PASE A LA PREGUNTA 6]**
9. **[NO LEA]** REHUSÓ **[PASE A LA PREGUNTA 6]**

5. **[SI NO SE HA HECHO UN MAMOGRAMA EN LOS ULTIMOS DOS AÑOS (antes de Abril de 1997) O "NO" a la pregunta 4 (NO TIENE PLANEADO HACERSE UNO EN LOS PRÓXIMOS 12 MESES]:**

Mis próximas preguntas son acerca de las razones por las que las mujeres no se hacen sus mamogramas. Por favor dígame si alguna de estas son las razones por las que usted(no ha hecho/ no esta planeando) hacerse un mamograma. Por favor conteste sí o no.

a. Le preocupa el costo.
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

b. No le gustó el mamograma que se hizo anteriormente.
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

c. No tiene manera de llegar allí.
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

d. No tiene a nadie que cuide de sus niños.
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

e. La cita on el medico toma mucho tiempo.
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

Otra vez, estas son algunas razones por las que algunas mujeres no se hacen los mamogramas. ¿Son algunas de estas razones las suyas?

f. El doctor no habla mi idioma.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

g. Necesita un intérprete.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

h. Tiene miedo de encontrar algo malo.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

i. Es vergonzoso hacerse esa clase de examen.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

j. Los doctores no comprenden a las mujeres de su raza.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

k. Le preocupa que el técnico de rayos-x podría ser hombre.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

l. Se olvidó de hacer una cita.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

m. Su Esposo no quiere que se lo haga.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

n. No tiene seguro médico.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

6. ¿Sabe dónde acudir si quisiera un mamograma este mes?
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

7. Ha tenido alguna vez un examen de los senos hecho por un doctor o enfermera? Un examen de los senos es cuando un doctor o enfermera le palpan los senos para sentir si tiene o no bolitas.
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

[SI ES SÍ]:

7a. Hace cuanto tiempo tuvo usted su último examen de los senos?
Años_____(Menos de un año = 00)(2 digitos para el codigo del año)
[SI ES MENOS DE UN ANO, DOCUMENTE CUANTOS ANOS]
Meses_____(01-12)

8. ¿Hay un doctor al que usted visita siempre que esta enferma o cuando necesita una revisión médica?
    1. Si
    2. No
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

9. Mis próximas preguntas son acerca de las cosas que la gente dice algunas veces de los mamogramas. Estas son opiniones y no hay respuestas correctas o incorrectas. ¿Por favor dígame si usted está de acuerdo o desacuerdo?

a. Usted no necesita un mamograma si un doctor o enfermera le ha examinado los senos.
    1. Acuerdo
    2. Desacuerdo
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

b. Los mamogramas pueden conducir a una operación innecesaria de los senos.
    1. Acuerdo
    2. Desacuerdo
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

c. Usted se haría un mamograma si su doctor le dijera que es importante.
    1. Acuerdo
    2. Desacuerdo
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

d. Usted no se haría un mamograma si le toma más de una hora para llegar allí (a la clínica).
    1. Acuerdo
    2. Desacuerdo
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

e. Haciéndose un mamograma cada año le dará un sentiolo de control sobre su salud.
    1. Acuerdo
    2. Desacuerdo
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

f. Usted se haría un mamograma solamente si tiene un problema en los senos.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

g. Los mamogramas son exámenes médicos muy comunes.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

i. Será bueno para su familia si usted se hace un mamograma.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

j. Mamogramas regulares le dan tranquilidad mental acerca de su salud.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

k. Un mamograma es una buena manera de cuidar de su persona.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

l. Una mujer debe hacerce un mamograma aun cuando no haya habido cáncer del seno en su familia.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

m. Los mamogramas son más beneficiosos cuando usted se hace uno cada año.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

n. Los mamogramas son seguros.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

o. Usted está muy ocupada para hacerce un mamograma.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

p. La mamografía no es un examen beneficioso para las mujeres de su edad.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

q. Los mamogramas cuestan mucho para usted.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

r. Un mamograma podría doler o ser incómodo.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

s. Usted no está preocupada acerca del cáncer del seno.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

t. Usted no necesita un mamograma porque está saludable.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

u. Hacerse un mamograma es demasiado problema.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

v. A su edad usted no necesita un mamograma.
   1. Acuerdo
   2. Desacuerdo
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

10. Durante los pasados 12 meses, ¿alguien de nuestro programa BACCIS platicó con usted para pedirle que se hiciera un mamograma? (alguien que le dio una pluma BACCIS blanca, pacha, con un magneto o que se la envió por correo. También, alguien de nuestro programa la podria haber llamado... ¿se recuerda?)
    1. Si
    2. No **[PASE A LA PREGUNTA 11]**
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

[SI ES SÍ]:

a. Le gustó hablar con esa persona?
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

b. Ella fue de utilidad para usted?
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

c. La convenció para que se hiciera un mamograma?
   1. Si
   2. No
   7. **[NO LEA]** NO APLICA
   8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
   9. **[NO LEA]** REHUSÓ

11. Durante los pasados 12 meses, ¿alguna <u>otra</u> mujer que usted conoce le ha platicado acerca de hacerse un mamograma?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

a. Era ella una voluntaria con nuestro Programa?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

[Si es SI or Not Sure]:

b. La convenció para que se hiciera un mamograma?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

12. Durante los pasados 12 meses, ¿ha tratado usted de obtener un mamograma gratis solo para encontrarse de que no califica?

1. Si
2. No
3. **[NO LEA]** Otro **(ESPECIFIQUE):** _____
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

[Si es SI]:

12a. Cual fue la razon?

1. **[NO LEA]** Edad
2. **[NO LEA]** Igreso
3. **[NO LEA]** Otro **[ESPECIFIQUE]:** _____

13. Estas son preguntas sobre seguro médico. Conteste sí o no a cada una de estas preguntas.

Tiene usted:

a. Medicare (Este es un plan de salud del govierno que paga por gastos medicos de personas mayores de 65 años, o personas con una incapacidad física)

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

b. MediCal(Este es un plan de salud del govierno estatal que paga por gastos medicos de personas con bajos ingresos o con una incapacidad física)

1. SÍ
2. No
97. **[NO LEA]** NO APLICA
98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
99. **[NO LEA]** REHUSÓ

[Si es SI por MediCal]
Tiene usted:

(i) Contra Costa Health Plan
1. SÍ
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

(ii) Blue Cross Health Plan
1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

c. Seguro médico que usted, su familia, o su empleador paga
(Nombre de la compañia:_____)

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

d. Basic Adult Care (BAC del Condado de Contra costa)

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

e. **[Si TODOS son No to 13a through d]:** De acuerdo a todo lo que usted me ha dicho, Usted no tiene seguro médico de ninguna clase. No incluyendo seguro dental o de visión, tiene usted un seguro médico que paga por sus visitas a su médico por medio de un plan que yo no haya mencionado?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

14. Cuándo usted visita al doctor, ¿tiene usted que pagar con su propio dinero?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

Tengo unas pocas preguntas más.

15. ¿En qué país nació?

1. Estados Unidos
2. México
3. Cuba
4. El Salvador
5. Colombia
6. Argentina
96. Otro [**ESPECIFIQUE**]:_____
97. **[NO LEA]** NO APLICA
98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
99. **[NO LEA]** REHUSÓ

15a. ¿Cuántos años tenía cuando se vino a vivir a Estados Unidos por primera vez?

___Edad cuando llego (If less than 1 year, code - 1. Logical range = 1 - 90)

97. **[NO LEA]** NO APLICA
98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
99. **[NO LEA]** REHUSÓ

15b. En total,¿Cuántos años ha vivido en Estados Unidos?

___Años (If less than 1 year, code -1. Logical range = 1 - 90)

97. **[NO LEA]** NO APLICA
98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
99. **[NO LEA]** REHUSÓ

16. Por lo general, ¿qué idioma(s) habla usted? **[Marque todos los que aplican]**

a. Inglés_____
b. Español_____
c. Otro **[ESPECIFIQUE]**:_____

[Si habla otro idioma/ademas de Inglés]:

16a. ¿Qué tan bien habla el Inglés?

1. No lo habla
2. Mal
3. Regular
4. Bien
5. Como hablante nativo
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

b. Por lo general,¿que idioma(s)lee usted?

1. Solamente Inglés
2. Español mejor que Inglés
3. Ambos por igual
4. Inglés mejor que Español (otro idioma)
5. Solamente Español (otro idioma)
6. Otro **[ESPECIFIQUE]**: _____
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

c. ¿Qué idioma(s) habla usted usualmente en su casa?

1. Inglés solamente
2. Español(u otro idioma) mejor que Inglés
3. Ambos por igual
4. Inglés mejor que Español (otro idioma)
5. Solamente español(otro idioma)
6. Otro **[ESPECIFIQUE]**:_____
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

d. ¿Qué idioma(s) habla usted usualmente con sus amigos?

1. Inglés solamente
2. Español(otro idioma) mejor que Inglés
3. Ambos por igual
4. Inglés mejor que Español(otro idioma)
5. Solamente español(otro idioma)
6. Otro **[ESPECIFIQUE]**:_____
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

17. ¿Cuántos años de escuela completó usted?

Si la participante dice[el grado], codifique de la manera siguiente:
Elementary=6; Junior High=8; High School/GED=12; Some college/Vocational School=14; College Graduate=16; Master's Degree=18; MD,PhD,JD,DDS=20

____Años

18. ¿Es usted dueña de su casa?
    1. Si
    2. No
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

19. En total, incluyéndose usted, ¿cuántas personas viven en su casa?
    _____Número de personas
    97. **[NO LEA]** NO APLICA
    98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    99. **[NO LEA]** REHUSÓ

20. Estas son mis últimas preguntas. Ahora voy a preguntarle sobre los ingresos de su casa. Puede ser difícil calcularlos, pero haga lo posible. Esta información es completamente confidencial. Sumando todos los ingresos de todos los mienbros de su hogar: (sueldos, Seguro Social, pensiones de jubilados, beneficios de desempleo o por incapacidad), ¿cuál de estas categorias le corresponde mejor al total de ingresos de su hogar del año pasado (1998)? Eran:

    1. Menos de $5000
    2. $5,001 - $10,000
    3. $10,001 - $20,000
    4. $20,001 - $30,000
    5. $30,001 - $40,000
    6. $40,001 - $50,000
    7. $50,001 o mas
    96. **[NO LEA]** PARTICIPANTE SOLAMENTE DIÓ EL INGRESO PROPIO
    97. **[NO LEA]** NO APLICA
    98. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    99. **[NO LEA]** REHUSÓ

21. Recibe usted SSI (Ingreso de Seguridad Suplementaria o cheque dorado)?
    1. Si
    2. No
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

Este es el final del cuestionario, pero me gustaria saber si :

22. Necesita ayuda para obtener un mamograma ahora?
    1. Si
    2. No
    7. **[NO LEA]** NO APLICA
    8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
    9. **[NO LEA]** REHUSÓ

22a. **[Si es SI]:** Quiere que pedir a una persona de nuestro personal que la llame en las próximas dos semanas?

1. SÍ
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

Muchas gracias por completar estas preguntas.

23. ¿Estaría bien si nos comunicamos con usted alguna otra vez para otra encuesta?

1. Si
2. No
7. **[NO LEA]** NO APLICA
8. **[NO LEA]** NO SABE/ NO ESTÁ SEGURA
9. **[NO LEA]** REHUSÓ

Muchas gracias otra vez por su tiempo.

Interviewer comments:

_____ Interviewer _____ Date

NORTHERN CALIFORNIA CANCER CENTER

32960 Alvarado-Niles Road, Suite 600, Union City, CA 94587 ♦ (510) 429-2500 ♦ FAX (510) 429-2550

HUMAN SUBJECTS REVIEW COMMITTEE
MEMO OF ACTION TAKEN

TO: **Rena Pasick, Dr. PH** **DATE: 6/25/99**

FROM: **Leila L. Colmen** LLC

SUBJECT: **Breast Cancer Outreach for Underserved Women (BACCIS II)**
Cancer Screening, Managed Care and the Underserved (Pathfinders) - CORE B

Date of Committee Action: 6/3/99

The Human Subjects Review Committee (HSRC) of the Northern California Cancer Center has reviewed the above referenced research projects and has made the following determination:

_____ Human Subjects are not at risk.

__X__ The submissions were approved as presented.

_____ The submission was approved subject to the changes listed on the attached page. Please make the modifications indicated and forward a copy of the modified document(s) to my attention.

_____ Action on the submission was deferred pending clarification of those items described on the attached page. We will place the item on the agenda of the next scheduled meeting and will inform you of the date.

This determination will expire on 6/3/2000. If the project is to continue beyond that date, it must be reviewed not less than on an annual basis and in accordance with the Cancer Center's Multiple Project Assurance.

Please note that any survey questionnaires or consent forms need to be brought before the HSRC before implementation of the project.

Any modification to the study that affects the participation of human subjects must receive prior approval from the HSRC.

Any complications related to subject participation, including adverse drug reactions and subject complaints, must be reported immediately to the HSRC. Please submit this information to me.

cc: HSRC File

OMB No. 0925-06

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROTECTION OF HUMAN SUBJECTS ASSURANCE/CERTIFICATION/DECLARATION

☐ ORIGINAL ☒ FOLLOWUP ☐ EXEMPTION (previously undesignated)

☒ GRANT ☐ CONTRACT ☐ FELLOW ☐ OTHER

☐ New ☐ Competing continuation ☐ Noncompeting continuation ☐ Supplemental

APPLICATION IDENTIFICATION NO. *(if known)*
DAMD 17-96-1-6070-01-1

POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act, implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY

Breast Cancer Outreach for Underserved Women (BACCIS II)

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Rena Pasick, Dr. PH, Principal Investigator

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(see reverse side)*

4. HHS ASSURANCE STATUS

☒ This institution has an approved assurance of compliance on file with HHS which covers this activity.

M-1380 Assurance identification number 01-XB IRB identification number

☐ No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

☒ This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. *(See reverse side of this form.)*

6/3/99 Date of IRB review and approval. *(If approval is pending, write "pending." Followup certification is required.)*
(month/day/year)

☒ Full Board Review ☐ Expedited Review

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification *(Form HHS 596)* will be submitted.

☐ Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ *(insert paragraph number of exemption in 46.101(b), 1 through 5)*, but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO. Northern California Cancer Center 32960 Alvarado-Niles Road, Suite 600 Union City, CA 94587 (510) 429-2500	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL *(print or type)* Leila L. Colmen Director, Administration	NAME AND TITLE OF OFFICIAL *(print or type)*
SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)* Leila L Colmen 6/28/99	SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)*

HHS 596 (Rev. 1/82)

(If additional space is needed, please use reverse side under "Notes.")

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(from front side)*

According to 45 CFR 46.121, if an application is made to HHS requiring certification and involving use of an investigational new drug or device, additional information is required. In addition, according to 21 CFR 312.1(a)(2), 30 days must elapse between date of receipt by FDA of Form FD-1571 and use of the drug, unless the 30 day delay period is waived by FDA.

3a. INVESTIGATIONAL NEW DRUG EXEMPTION *(if more than one is involved, list others below under NOTES):*

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER	NUMBER ISSUED

3b. INVESTIGATIONAL DEVICE EXEMPTION:

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (ii) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a nonsignificant risk device; and (2) the IRB has approved the study. *(Check applicable box.)*

☐ The IRB agrees with the sponsor that this device is a nonsignificant risk device.

OR

☐ The IDE application was submitted to FDA on *(date)*_____. Number issued_____.

NOTES: